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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,414	06/14/2001	Jens Nielsen	NIELSEN 4	2283
1444	7590	12/17/2003	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			LEFFERS JR, GERALD G	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,414

Applicant(s)

NIELSEN ET AL

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/23/01.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 73-89) in the papers filed 9/2/2003 is acknowledged. The traversal is on the ground(s) that the methods of using the microbial cells of Group II should properly be joined with Group I because the methods of Group II necessarily comprise the same special technical feature as the cells used in the methods. This argument is found persuasive in the instant application. Therefore, claims 90-92 have been rejoined with claims 73-89.

The response filed on 9/2/03 amended several of the claims to correct dependency or typographical errors (e.g. claims 82-84, 90). Claims 73-92 are pending and under consideration in the present application.

Information Disclosure Statement

Receipt is acknowledged of an information disclosure statement, filed 4/23/2001. The signed and initialed PTO Form 1449 has been mailed along with this action.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, the abstract is over 150 words in length, uses legal phraseology (i.e. "said") and is not concisely drawn to the subject matter claimed.

Claim Objections

Claims 73-92 are objected to because of the following informalities: each of the claims is not a complete sentence as it lacks an article at the beginning of the claim (e.g. "A" or "The").

Appropriate correction is required.

Claim 90 is objected to because of the following informalities: it is grammatically incorrect for the claim to recite, "is producing". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Each of the rejected claims is drawn to a recombinant microbial cell wherein the cell comprises a first nucleic acid encoding a first enzymatic activity (e.g. protein) that "controls

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assimilation” of a nitrogen nutrient source operatively linked to a nonnative “transcription signal” (e.g. promoter) that results in overexpression of the first protein. The cell can optionally comprise a second nucleic acid sequence encoding a second protein that controls assimilation of a nitrogen source where the second nucleic acid sequence is operatively linked to a nonnative promoter that overexpresses the second protein. The cell necessarily comprises a “third” nucleic acid encoding a third protein or enzymatic activity that controls assimilation of a nitrogen source wherein the level of expression of the third activity is less than when its coding sequence is operatively linked to its own promoter. The microbial cell can be literally of any source (e.g. fungal, yeast or bacterial). The nitrogen source “controlled” by the different proteins is not necessarily the same molecule or compound (e.g. ammonia) and can be any substance that might be a nitrogen source to be utilized or “assimilated” in some fashion. There is not necessarily any functional linkage between the different enzymatic activities recited in the claims. The claims thus encompass an incalculable number of different combinations of genes encoding proteins or biochemical activities that are in some way involved in the “assimilation” and/or utilization of a nitrogen nutrient source or sources.

The instant specification provides little significant guidance with regard to specific embodiments of the claimed invention wherein different enzymatic activities are manipulated to control the utilization of a nitrogen source (e.g. yeast cells, glutamine or glutamate synthase activity, etc.). These examples and guidance do not provide a basis for the skilled artisan to envision a sufficient number of specific embodiments of the claimed cells to describe the enormously broad genus of such cells. Therefore, the skilled artisan would reasonably have concluded applicants were not in possession of the claimed invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 73, 91-92 are vague and indefinite in that the metes and bounds of the term “expression signal” are unclear. The term does not appear to be clearly defined in the specification. It appears the term is intended to specify a “promoter”, rather than other types of regulatory sequences that might be considered to be encompassed by the term (e.g. an mRNA stabilization sequence, a polyA termination signal, etc.).

Claim 73 is vague and indefinite in that the metes and bounds of the phrase “...enzyme activity controlling assimilation of a nitrogen source” are unclear. First, it is unclear if the term “enzyme activity” necessarily refers to a protein encoded by a nucleic acid. Second, the metes and bounds of the terms “controlling” and “assimilating” are not clear. Would any effect on the “assimilation” of the nitrogen nutrient source constitute “controlling”? Does assimilation necessarily mean that the cell metabolizes the nitrogen nutrient source, or can it encompass some other type of activity (e.g. “fixing” the nitrogen nutrient source in some manner in the external environment of the cell)?

Claim 73 is vague and indefinite in that the metes and bounds of the term “and/or” as applied between elements (i) and (ii) are unclear. If the first enzyme activity is not present (i.e. in the case of “or”), how can the activity of part (ii) be the “second” activity?

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Claim 73 is further vague and indefinite in that the metes and bounds of the phrase “as compared to the expression of the third enzyme activity when the third enzyme activity is associated with its native expression signal” are unclear. The phrase is unclear in that it implies that the nucleic acid sequence encoding the third enzyme activity may necessarily be operatively linked to a nonnative promoter. Yet the claim does not explicitly state anywhere else in the claim that the sequence encoding the third enzyme activity is linked to a nonnative promoter.

Claim 74 specifies that different enzymatic reactions are “operatively linked”. How closely related do two biochemical reactions have to be in order to be “operatively linked”? Can they be several steps in a metabolic pathway separated from one another and still be considered “operatively linked” so long as the result of one reaction tangentially affects the second reaction?

Claim 80 is vague and indefinite in that the metes and bounds of the term “gluta 30 mate” are unclear, although it appears the terms is meant to read as “glutamate”.

Claim 90 is vague and indefinite in that the metes and bounds of the term “suitable” as applied to growth media or metabolites are unclear. The term “suitable” is inherently indefinite and open to interpretation. It would be remedial to amend the claim language to clearly indicate what is intended by the term “suitable” in each case.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

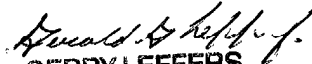
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

Ggl


GERRY LEFFERS
PRIMARY EXAMINER